

# AMERICAN MEDICAL TECHNOLOGIES, INC.

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## 510(k) Summary K963808

**(a) (1) Submitter's name, address**

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**(2) Device trade or proprietary name:** CHOICE Powered Wheelchair

**Device common or usual name or classification name**

<u>Product Nomenclature</u>	<u>Classification Number</u>	<u>Class</u>	<u>Panel</u>
WHEELCHAIR, POWERED	89 ITI	II	PHYSICAL MEDICINE

**(3) Substantial Equivalence**

The CHOICE powered wheelchair is substantially equivalent in safety, efficacy, technology and intended use to its predicate model EXCELSIOR SR powered wheelchair currently marketed by American Medical Technologies as well as numerous other devices such as the Permobil, Inc. 'Chairman' power wheelchair, the Sunrise Medical 'Quickie P300' power wheelchair [K900330] and the Invacare 'Action Storm' power wheelchair [K940051].

**(4) Description of the new device**

The CHOICE powered wheelchair is manufactured using fabricated steel for the power base and seat assemblies. All components determined to be a permanent part of the structural frame or seating are welded. Any parts which are required to be removable for service or adjustment to perform it's function are attached with locking fasteners.

The CHOICE is supplied with two, 12 volt gel cell batteries, either Group 22, Group 24 or Group 27 with a #891 style post, wired in series to provide 24 volts DC [Vortex Batteries, Doraville, GA]. The controller of the device is completely manufactured, tested and certified by Penny & Giles, Dorset, UK, which also contains the software programming and power output to operate the chair's drive motors, as well as interface to various optional features. A joystick, 'sip-n-puff', or alternative control mechanism is used to direct the function of the controller. Two drive motors are located on the power base and attached to a gearbox which provides the appropriate speed control and torque for the chair through a direct drive to the drive wheels.

Electrically controlled actuators are used to provide the various movement features of the seating system, including: reduced-shear recline, power elevating leg rests, 'tilt-in-space' and seat elevation. The chair is recharged overnight using a dual-mode, fully automatic battery charger [Lester Electrical, Lincoln, NE Model Number 24EL8, 120V/60Hz] certified for safety and fire resistance in compliance with current ANSI/RESNA standards.

**(5) Intended use of the device.**

The CHOICE powered wheelchair is intended to provide mobility for a person who, due to medical reasons, the debilitating nature of some illnesses, because of accident, injury and/or subsequent paralysis, is either missing or unable to use the lower extremities. Some, but not all of the specific indications for use of a power wheelchair are: paraplegia, quadriplegia, ALS, muscular dystrophy, muscular sclerosis, lower limb amputation and any one or more of numerous neurological or muscular diseases which render the limbs too weak or unstable for normal use.

**(6) Technological characteristics of the device.****Sizes, configurations and functions of each device component**

The CHOICE is available with either a 16- or 18-inch wide base in combination with seats widths from 14- to 20-inches and seat depths from 14- to 24-inches to accommodate most users.

The CHOICE is available as a basic, powered wheelchair with a fixed seat, or with any or all of the following seating and positioning options:

- seat elevator providing 8 to 10 inches of vertical lift
- reduced-shear recliner, with or without power elevating leg rests
- 'Tilt-in-Space', 0 to 55 degrees

Both tilt and recline are used to provide pressure relief and, can be used either in combination or independently as necessary.

The elevator feature provides many vocational and functional benefits associated with position. While not providing any physically therapeutic benefit, the practical value tends to make this feature very desirable for those persons with enough use of arms and hands.

**Specifications**

Weight:	199 lb. w/o batteries, 270 to 300 lb. with batteries
Length:	34 inches, plus footrest
Height:	19.5 inches, floor to seat
Overall Width:	customized, from 26 to 28 inches
Seat Width:	customized, from 14 to 22 inches
Front Wheels:	14" OD x 3" wide
Rear Wheels:	8" OD x 2" wide

**(b) (1) Summary of nonclinical tests submitted with the premarket notification for the device.**

The CHOICE was tested in accordance with the ANSI/RESNA Standard, Wheelchairs - Testing of Power and Control Systems for Electric Wheelchair. WC/14, December 1991, parts 00, 01, 02, 03, 05 and 10:

**WC 01: Static Stability Test Results**

Test Number	7.1		7.1		7.2	7.3	
Chair position	Downhill		Uphill		Uphill	Sideways	
Wheel locks	locked		locked		unlocked	locked	
Action	Slide	Tip	Slide	Tip	Tip	Slide	Tip
Block Size	0"	1.6"	0"	0"	1.6"	3.9"	1.6"
seat position fully down	no slide	17.5°	18°		43°	49°	22° 35°
seat position fully up	no slide	12°	18°		43°	49°	19° 26°

**WC 02: Dynamic Stability Test Results**

Test Number	7.1	7.2	7.3
description	Up ramp with max. acceleration	Braking down 5 deg. [lift, tip, slide, stable]	Turning [lift, tip or stable]
seat position fully down	22° to lift unit is front-wheel-drive	stable. unit is equipped with anti-tip devices	stable. unit is equipped with anti-tip devices
seat position fully up	19° to lift unit is front-wheel-drive	stable. unit is equipped with anti-tip devices	stable. unit is equipped with anti-tip devices

**WC 03: Stopping Distances from Maximum Speed****Maximum Effort (Max) and Automatic (Auto) Braking**

Test Number		7.2.1a		7.2.1b		7.2.1c	
Maximum Speed (mph)		Forward, Horizontal Plane (feet)		Backward, Horiz. Plane (feet)		Forward, down 5° Incline (feet)	
Forward	Reverse	Max	Auto	Max	Auto	Max	Auto
5.2	1.3	3.3	3.8	2.3	2.8	3.3	3.8

**WC 05: Overall Dimensions**

5.1.1		5.1.2		5.1.3		5.1.4	
Overall length with leg support and footrest		Overall length without leg support and footrest		Overall width		Overall height with backrest in upright position	
inches	mm	inches	mm	inches	mm	inches	mm
45	1143	31.5	800	26	660	41	1041

**WC 05: Overall Dimensions (turning space)**

7.1		7.2	
Turning radius		Turnaround width between limiting walls	
inches	mm	inches	mm
24	610	44	1118

**WC 10: Obstacle Climbing Test Results**

7.1		7.2		7.3		7.4	
Forward no run-up		Backward no run-up		Forward 20 inch run-up		Backward 20 inch run-up	
inches	mm	inches	mm	inches	mm	inches	mm
2.25	57.15	2.25	57	3	76	2.25	57

Additionally, the CHOICE was tested in accordance with the ANSI/RESNA "Proposal, Addition to ANSI/RESNA WC/14 - Electromagnetic Compatibility Requirements for Powered Wheelchairs and Motorized Scooters", Ver. 1.5; 1/11/94 to conclude that the CHOICE is fully compliant with the EMC specification requirements with a test level of 40 V/m.

The CHOICE was also tested for compliance to the specification, Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment, also related to the above ANSI/RESNA Proposal to determine that the CHOICE meets or exceeds all requirements of the test specification.

**(b) (2) Summary of clinical tests submitted with the premarket notification for the device.**

No clinical tests were submitted with the pre-market notification for the CHOICE Powered Wheelchair.

**(b) (3) Conclusions drawn from the clinical and nonclinical trials.**

Analysis of the comparison of design, function and features of the CHOICE Powered Wheelchair to other devices currently legally marketed for the same intended use, together with the results of testing conducted to assess the CHOICE's compliance with existing ANSI/RESNA standards for powered wheelchairs demonstrates the CHOICE to be substantially equivalent to these predicate devices in terms of safety, efficacy, intended use and technology.